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June 5, 2023

#### Via ECF

The Hon. Robert B. Kugler
United States District Judge
USDC, District of New Jersey
Mitchell H. Cohen Building & U.S. Courthouse
4<sup>th</sup> & Cooper Streets, Room 1050
Camden, NJ 08101

Special Master the Hon. Thomas Vanaskie Stevens & Lee 1500 Market Street, East Tower, 18th Floor Philadelphia, PA 19103

Re: In re Valsartan, Losartan, and Irbesartan Products Liability Litigation USDC, District of New Jersey, No. 1:19-md-2875-RBK-SAK

Dear Judge Kugler and Judge Vanaskie:

I write on behalf of the Defendants' Executive Committee to provide Defendants' positions with respect to the topics on the agenda for the conference with the Court on Wednesday, June 7, 2023. Defendants do not anticipate that any of the matters to be discussed at the conference will require confidentiality.

#### 1. Plaintiffs' Class Notice Proposal

Plaintiffs filed their Motion for Approval of Form and Manner of Class Notice [Dkt. 2375] ("Class Notice Plan"), on May 10, 2023. Defendants filed their Opposition to the Class Notice Plan [Dkt. 2412] on May 26, 2023. Plaintiffs' reply is presently due on June 7, 2023 under Case Management Order No. 32.

Plaintiffs' counsel notified defense counsel by electronic mail on May 31, 2023 that, in lieu of a reply, Plaintiffs intend to revise their Class Notice Plan to include individualized notice to class members and to address other issues raised in Defendants' Opposition. Plaintiffs' counsel proposed that the parties jointly request a revised briefing schedule for class notice to account for Plaintiffs submitting a revised Class Notice Plan, as well as Defendants' response to the revised Class Notice Plan and Plaintiffs' reply. Defense counsel responded the same day that Defendants would work with Plaintiffs on a revised schedule and requested Plaintiffs' proposed schedule. Plaintiffs' counsel responded on June 2, 2023, that Plaintiffs are still working on determining what schedule makes sense.

In light of these developments, Defendants anticipate that there will not be substantive argument concerning the Class Notice Plan at the June 7 Case Management Conference, and anticipate there may be a discussion regarding the briefing schedule for Plaintiffs' revised Class Notice Plan. Defendants will be prepared to discuss that subject, together with any questions the Court may have concerning Plaintiffs' Class Notice Plan or Defendants' Opposition.

#### 2. Plaintiffs' Discovery Requests directed to the Retail Pharmacy Defendants

The Pharmacy Defendants are continuing to work with Plaintiffs to understand the scope of the discovery Plaintiffs seek from them, but Plaintiffs keep changing their requests, rendering fulsome and timely responses difficult or impossible. Nonetheless, in today's letter, the Pharmacy Defendants provide the following update regarding ongoing discovery issues and attempt to respond to the three new issues Plaintiffs identified for discussion.

#### A. CMO 32 Discovery

CMO 32 ordered the Pharmacy Defendants to provide to plaintiffs the following information relating to class certification claims:

- 6.1.1 amounts TPPs paid for VCDs
- 6.1.2 retailers' costs and profits for VCDs
- 6.1.3 previously-redacted retailer identifiers of ConEcoLoss members

ECF No. 2343. As noted at the April 26 in-person conference, the Pharmacy Defendants were committed to meeting and conferring with Plaintiffs regarding the interpretation of that order and the feasibility of productions. Those efforts are ongoing, and Plaintiffs are currently evaluating the Pharmacy Defendants' May 22 proposal to Plaintiffs, which the Pharmacy Defendants hope will resolve most, if not all, of the parties' open issues.

Additionally in CMO 32, the Court granted Plaintiffs' request for "further targeted discovery and depositions of retailer custodians and FRCP 30(b)(6) deponents," with scheduling to occur at the upcoming Case Management Conference. *Id.* Again, the Pharmacy Defendants and Plaintiffs are continuing to meet and confer regarding custodial discovery and depositions. If those meet and confer efforts are not successful, the parties have agreed to follow the briefing schedule used for the dispute between Plaintiffs and the Wholesalers, with oral argument via Zoom before Judge Vanaskie on July 6, 2023. Special Master Vanaskie entered that order today. ECF No. 2416. The parties believe that the timing of custodial discovery can be determined before or by the July 6, 2023 oral argument, as the parties are still meeting and conferring regarding the timing of discovery, which in part depends on scope, and may be able to reach agreement on a schedule. Nonetheless, the Pharmacy Defendants will be prepared to discuss a schedule for custodial discovery and depositions if the Court desires at the upcoming conference this Wednesday, June 7.

### **B.** New Requests from Plaintiffs

In exchanging topics with Plaintiffs for the upcoming conference, Plaintiff identified that they plan to bring three new issues to the Court's attention: (i) amendment of the HIPAA order to include telephone numbers, (ii) production of consumer class member identifiers in other databases besides pharmacy dispensing records (e.g., customer loyalty data, membership data, etc.); and (iii) production of third party payor identities (not the amounts paid, which is addressed separately). See June 1, 2023 Email from Dave Stanoch, attached as Exhibit A. None of these matters is ripe for resolution before the Court, as Plaintiffs just asked for this information two business days ago, such that the Pharmacy Defendants are still discussing these issues with their clients in order to meet and confer with Plaintiffs. The Pharmacy Defendants propose that the Court encourage the parties to continue to meet and confer, and, if they cannot obtain resolution, brief these three issues as well according to the briefing schedule just entered by Special Master Vanaskie, with oral argument to be held July 6, 2023. See ECF No. 2416.

#### 1. Telephone numbers

Plaintiffs' recent request for telephone numbers follows a pattern of Plaintiffs seeking everchanging information from the Pharmacy Defendants with little notice to them. In mid-May, Plaintiffs represented the only identifiers they seek are name, address and email. *See* May 10, 2023 Letter from Adam Slater (ECF No. 2374) ("Plaintiffs have agreed to narrow this information to that necessary to effectuate notice, including: name, address, and email. Plaintiffs do not seek other identifying information (e.g., birth date, SSN, etc.)."; May 15, 2023 Letter from Adam Slater (ECF No. 2376) ("Finally, in terms of identifiers for consumer economic loss class plaintiffs (CMO No. 32, at ¶ 6.1.3), the Parties have agreed to narrow this information to that necessary to effectuate, notice, including: name, address, and email.") Plaintiffs later requested that the Retail Pharmacy Defendants provide data of birth, so the Retail Pharmacy Defendants agreed and included that within the proposed order regarding protected health information under HIPAA. On May 30, the Court entered that order, which reflected the parties' agreement following this extensive meet and confer process. (ECF No. 2413).

Just a day later, on May 31, Plaintiffs reached out to advise the Pharmacy Defendants that Plaintiffs now also seek to have the Retail Pharmacy Defendants include telephone numbers as an additional data pull within the structured dispensing data, and a day after that, sought to amend the HIPAA order because those telephone numbers would be protected health information. *See* June 1, 2023 Email from Dave Stanoch, attached as Exhibit A.

The Pharmacy Defendants have concerns about whether the production of telephone numbers is necessary, given Plaintiffs' initial class notice plan did not involve direct communications to class members. Notice via telephone, whether robocalls or text messages, may be unnecessary and intrusive, especially given the demographics of the class members, who may not use text messaging frequently or reliably. Likewise, receiving a robo-dialed call is very intrusive to many consumers as contrasted with a postcard or mailer. Given these concerns, and the fact that no notice plan actually *using* telephone numbers is pending, the Retail Pharmacy Defendants do not believe this issue is ripe for decision. In any event, if phone numbers must also

be included in the Pharmacy Defendants production, the Court's previously approved HIPAA order will need to be amended, and the Pharmacy Defendants will need to revise their collection requests so that this data can be queried, pulled and produced alongside each consumer's name, address and email. As noted above, counsel for the Pharmacy Defendants are still meeting with clients to discuss this issue, given the timing of Plaintiffs' recent request, and will meet and confer with Plaintiffs on this further.

### 2. Consumer Class Member Identifiers in Databases Outside of Dispensing Records

Plaintiffs recently suggested that information within the dispensing records may be insufficient to identify every piece of possible contact information for a putative consumer economic loss class member, and that the Pharmacy Defendants should engage in herculean discovery efforts in an effort to *potentially* provide additional contact information for those putative class members to the extent that such contact information is not already contained within the dispensing records.

First, this entirely new request from Plaintiffs is premature, given that production of the identifiers within the dispensing data (including telephone numbers if ordered) has not yet occurred. It may be that Plaintiffs (and the Court) are entirely satisfied with the contact information available within that pull, such that this extravagant effort is entirely unnecessary. Plaintiffs' initial notice plan did not contemplate direct-to-consumer notice, and Plaintiffs have not yet put forward any type of notice plan that actually uses the dispensing data information the Pharmacies will soon be producing.

Second, the request is largely—or entirely—duplicative of the dispensing data pull. Some Pharmacy defendants may not have any additional information that is not within the dispensing data. If the dispensing data does not contain an email address for a putative class member, the pharmacy may not have *any* information from that consumer containing an email address, regardless of source. Given the late timing of this request from Plaintiffs, the Pharmacy Defendants have not fully investigated Plaintiffs' ask. But it is truly a fishing expedition to request this type of herculean data pull on the off chance that the current data pull *might* be insufficient to provide direct notice to consumers. Moreover, to date, no Defendant has argued that sending direct notice via the information contained in the Pharmacy Defendants' dispensing records – the best and true source for information about who is or is not a member of the class – is insufficient. That there *might* be different or additional email address or other contact information in a source outside that dispensing data does not justify pulling the loyalty records for potentially millions of consumers on the off chance that some additional information might be available.

Third, the request—if even possible—may be extremely burdensome and costly. In meeting and conferring about this topic, Plaintiffs have referenced loyalty card data pulls from the Zantac litigation. That litigation was postured much differently than this one, in that the Plaintiffs—on a periodic basis—provided customer identifying information (loyalty information, largely) for certain registered, unfiled plaintiffs, who then searched through purchase records to identify whether <u>over-the-counter ranitidine</u> was within the consumer's purchases. Loyalty records were *not* used to search for or identify an entire class of consumers who filled prescriptions

through the Zantac defendants' pharmacies (information that the dispensing data being produced by the Pharmacy Defendants in *this* litigation already reflects). Here, it is unclear what Plaintiffs even propose to have the Defendants do in terms of identifying putative class members from a data set outside the dispensing records. Even the limited endeavor in *Zantac* was extremely costly, burdensome, and time-consuming.

Again, this request is entirely new from Plaintiffs, and at a minimum, counsel for the Retail Pharmacy Defendants need to confer with their clients about what is even potentially feasible and then confer again with Plaintiffs. The Pharmacy Defendants suggest that this topic be included in the upcoming briefing schedule with Judge Vanaskie (*see* ECF No. 2416), or deferred even further beyond that, as it makes sense to consider this issue *only* after Plaintiffs have reviewed the information produced in connection with the dispensing data and formulated their new notice plan.

#### 3. Payor Information

Pharmacy Defendants have agreed to produce data reflecting the payment amounts received by third-party payors. Two business days ago, on June 1, Plaintiffs conveyed via email an additional request that the Pharmacy Defendants separately produce the "payor identities" (or TPP names), as a request separate from and in addition to their existing request for third-party payment amounts. *See* June 1, 2023 Email from Dave Stanoch, attached as Exhibit A.

The Retail Pharmacy Defendants need time to discuss this request with their clients in order to respond. The availability of this information may vary drastically from pharmacy to pharmacy, and may not exist at all within the dispensing data previously produced. Some Pharmacy Defendants may not possess the actual names of the underlying third-party payor health plans that are financially responsible for reimbursement. Other Defendants may possess that information, but not in a reasonably accessible manner. To the extent certain Defendants do have the identity of the actual third-party payor health plan at issue, that information may be a very highly confidential trade secret subject to contractual limitations on how it may be shared, so appropriate safeguards and notice procedures would need to be followed before it could possibly be shared.

The Retail Pharmacy Defendants do not believe this issue is ripe for resolution. To the extent Plaintiffs continue to insist on it, the Retail Pharmacy Defendants request that it be briefed and argued following the same briefing schedule recently entered by Judge Vanaskie for other issues facing the Retail Pharmacy Defendants. *See* ECF No. 2416.

#### C. Losartan/Irbesartan Discovery

Under CMO 32, as modified by Special Master Order 76, Plaintiffs were permitted to "propound initial discovery requests for losartan and irbesartan, that will be focused on . . . class certification" for economic loss issues (ECF 2343 at 3) by May 22, 2023. Plaintiffs did so, serving twenty-six such requests on May 22, 2023. But then, almost two weeks after the deadline, Plaintiffs served a second set of discovery on June 2, 2023 containing thirteen further requests for production (ECF 2414.) These requests, already untimely under the Court's scheduling orders,

also expanded the subject area of Plaintiff's discovery beyond class certification issues. CMO 32 sought to limit Plaintiffs to a specific timeframe and subject matter for initial losartan/irbesartan discovery. Plaintiffs' second set of requests exceed CMO 32 in both regards, and Pharmacy Defendants should not have to respond to these untimely and improper requests. Nonetheless, like the issues above, the Retail Pharmacy Defendants do not believe this issue is ripe for adjudication and simply raise it to preserve the issue.

### 3. Plaintiff Fact Sheet Deficiencies and Orders to Show Cause

### Cases Addressed at the April 26, 2023 Case Management Conference:

The Court issued three show cause orders returnable at the June 7, 2023 Case Management Conference:

- 1. *Deborah Bixler v. ZHP*, *et al.* 22-cv-6653
- 2. Estate of Steven Jiles v. ZHP, et al. 22-cv-5628
- 3. Diane Hardwick v. Aurobindo, et al. 22-cv-6397

The issues in the *Bixler* and *Jiles* matters are resolved, and the show cause orders may be withdrawn.

The issues in the *Hardwick* matter remain unresolved, but the parties agree to an extension of the show cause order until the next case management conference.

### **Second Listing Cases – Order to Show Cause Requested:**

Pursuant to CMO-16, the Plaintiff Fact Sheets in the below cases are substantially incomplete and contain core deficiencies. Each of these cases were previously listed on the agenda for a prior CMC. This list was provided to Plaintiffs' leadership on May 30, 2023, and a global meet and confer was held on June 2, 2023. Defendants have also been available for further discussion as needed. Accordingly, Defendants request that an Order to Show Cause be entered in each of these cases, returnable at the next case management conference, as to why these cases should not be dismissed.

Defense counsel will be prepared to address the individual issues with respect to each of these cases, to the extent necessary, during the June 7, 2023 Case Management Conference:

<sup>&</sup>lt;sup>1</sup> For example, Plaintiffs request discovery concerning "documents and communications regarding changes to the sourcing of generic drug products as a result of the [alleged] nitrosamine contamination." (ECF 2414, RFP No. 9.) These documents would address merits issues, not class certification issues.

<u>First Listing Cases – Remaining Core Deficiencies:</u>

|    | Plaintiff                                 | Civil<br>Action<br>No. | Law Firm           | Deficiencies  | Deficiency<br>Sent |
|----|---|------------------------|--------------------|---|--------------------|
| 1. | Ricky Young v.<br>ZHP, et al.             | 22-cv-<br>7210         | Bernstein Liebhard | Largely deficient PFS; Authorizations have to be addressed to providers, not a blank template; must be undated and witnessed where necessary. | 3/30/22            |
| 2. | Jacquelyn<br>Smason v. Doe                | 23-cv-194              | Nigh Goldenberg    | Need medical expenses.  | 4/3/23             |
| 3. | Rafael Feria v.<br>Teva, et al.           | 23-cv-485              | Nigh Goldenberg    | Need medical expenses.  | 4/4/23             |
| 4. | Thomas Fogarty<br>v. Aurobindo, et<br>al. | 21-cv-<br>13480        | Brown Chiari       | No PFS Filed  | PFS Due – 3/14/23  |
| 5. | Robert Janecek<br>v. ZHP, et al.          | 23-cv-538              | Nabers Law         | No PFS Filed  | PFS Due – 3/31/23  |

The following Plaintiff Fact Sheets contain core deficiencies which remain unresolved. This list was provided to Plaintiffs' leadership on May 30, 2023, and a global meet and confer was held on June 2, 2023. Defendants have also been available for further discussion as needed. This is the first time these cases have been listed on this agenda. Accordingly, Defendants are not requesting orders to show cause with respect to any of the below cases at this time and will continue to meet and confer to resolve these deficiencies.

| Plaintiff | Civil  | Law Firm | Deficiencies | Deficiency |
|-----------|--------|----------|--------------|------------|
|           | Action |          |              | Sent       |
|           | No.    |          |              |            |

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| 1. | Michael Goss v.<br>ZHP, et al.         | 22-cv-<br>6966  | Nigh Goldenberg        | Authorizations must be addressed to providers and insurance entitie(s). Not a blank template.              | 4/18/23 |
|----|--|-----------------|------------------------|--|---------|
| 2. | Cynthia Earney<br>v. Walmart Inc.      | 21-cv-<br>13479 | Parafinczuk Wolf       | Need authorizations  | 4/28/23 |
| 3. | Regina Johnson<br>v. ZHP, et al.       | 22-cv-<br>1881  | Moore Law Group        | Insurance authorization must be witnessed; need authorization for Independence Keystone.                   | 4/28/23 |
| 4. | Leslie Sturgill v.<br>ZHP, et al.      | 23-cv-612       | Bernstein Liebhard LLP | Largely deficient PFS  | 5/2/23  |
| 5. | Russell<br>Christian v.<br>Doe, et al. | 23-cv-861       | Oliver Law Group       | Need prescribing physician information; need to answer if making mental health claim; need authorizations. | 5/2/23  |

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| 6.  | Taffnie<br>Williams v.<br>Aurobindo<br>Pharma, et al. | 20-cv-<br>20380 | Donahey Law Firm | Need pharmacy records;<br>need healthcare<br>authorization                                     | 5/3/23  |
|-----|---|-----------------|------------------|--|---------|
| 7.  | E/O John Faragi<br>v. Hetero, et al.                  | 23-cv-<br>1166  | Fleming Nolen    | Largely deficient PFS; need medical expenses; need authorizations.                             | 5/19/23 |
| 8.  | Richard Parks v.<br>ZHP, et al.                       | 23-cv-857       | Levin Papantonio | Need medical expenses  | 5/19/23 |
| 9.  | George Cook v.<br>ZHP, et al.                         | 23-cv-643       | Nabers Law Firm  | Need to state when first diagnosed with HTN; health insurance authorization must be witnessed. | 5/20/23 |
| 10. | Lawrence<br>Addison v. ZHP,<br>et al.                 | 23-cv-339       | Hollis Law Firm  | All authorizations must be undated.  | 5/20/23 |

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| 11. | Sharon Thomas<br>v. Aurobindo<br>Pharma, Ltd. et<br>al. | 23-cv-<br>0338  | Nigh Goldenberg Raso &<br>Vaughn | No medical expense records uploaded; declaration is undated and is missing Plaintiff's printed name; necessary authorizations are signed but incomplete.  | 4/11/23 |
|-----|---|-----------------|----------------------------------|---|---------|
| 12. | Joseph George<br>v. Hetero, et al.                      | 12-cv-<br>12916 | Goldenberg Law, PLLC             | Largely deficient PFS; insufficient product ID information and background information; no response as to potential wage loss claim; no authorizations; no medical or pharmacy records; no signed declaration;                         | 5/20/23 |
| 13. | Michelle Worms<br>v. Hetero Labs,<br>et al.             | 20-cv-<br>19852 | Goldenberg Law, PLLC             | Largely deficient PFS;<br>insufficient product ID<br>information and background<br>information; no response as<br>to potential wage loss claim;<br>no authorizations; no<br>medical or pharmacy<br>records; no signed<br>declaration; | 5/11/23 |
| 14. | Robert Lee v.<br>Hetero Drugs, et<br>al.                | 20-cv-<br>19843 | Nigh Goldenberg                  | Largely deficient PFS;<br>insufficient product ID<br>information and background<br>information/medications;<br>insufficient authorizations,<br>no billing records   | 5/10/23 |
| 15. | Karl Bartels v.<br>Hetero Labs, et<br>al.               | 20-cv-<br>19869 | Nigh Goldenberg                  | Largely deficient PFS; no medical or pharmacy records; insufficient product ID information and background information; insufficient other exposures information; no authorizations; no signed declaration                             | 5/11/23 |

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| 16. | Seifert v. Mylan<br>Pharmaceuticals,<br>Inc., et al. | 22-cv-<br>06727 | Brown Chiari LLP               | Incorrect date on declaration (states that it was signed in 2013); areas of PFS left blank, see notice for complete listing | 5/30/2023             |
|-----|--|-----------------|--------------------------------|---|-----------------------|
| 17. | Tom Lemen v.<br>ZHP, et al.                          | 21-cv-740       | Law Office of Oscar<br>Alvarez | No PFS Filed  | PFS Due –<br>4/2/21   |
| 18. | James Magee v.<br>ZHP, et al.                        | 19-cv-<br>15858 | Pro Se                         | No PFS Filed  | PFS Due –<br>11/18/19 |
| 19. | Phyllis Axt v.<br>ZHP, et al.                        | 20-cv-<br>8050  | Douglas & London               | No PFS Filed  | PFS Due – 9/1/20      |
| 20. | William<br>Garewal v. ZHP,<br>et al.                 | 20-cv-<br>8421  | Rueb Stoller                   | No PFS Filed  | PFS Due –<br>9/7/20   |

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| 21. | Beatrice Meza v.<br>Hetero, et al.             | 20-cv-<br>8799  | Wiggins Childs       | No PFS Filed | PFS Due – 9/13/20     |
|-----|--|-----------------|----------------------|--------------|-----------------------|
| 22. | Jane Davis-<br>Nevaquaya v.<br>Hetero, et al.  | 20-cv-<br>14027 | Brown LLC            | No PFS Filed | PFS Due – 12/7/20     |
| 23. | Stacey Thomas<br>v. Hetero, et al.             | 19-cv-<br>21832 | Farris Riley         | No PFS Filed | PFS Due – 12/23/20    |
| 24. | Arnold Vander<br>v. ZHP, et al.                | 20-cv-<br>10244 | Rubin & Machado, Ltd | No PFS Fled  | PFS Due –<br>10/19/20 |
| 25. | E/O Barbara<br>Lipscomb v.<br>Rite Aid, et al. | 21-cv-<br>6574  | Carlson Law          | No PFS Filed | PFS Due – 5/24/21     |

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| 26. | Benjamin<br>Andrews v.<br>ZHP, et al.   | 21-cv-<br>10908 | Whitehead Law Firm | No PFS Filed | PFS Due – 7/7/21   |
|-----|---|-----------------|--------------------|--------------|--------------------|
| 27. | James Polk v.<br>ZHP, et al.            | 21-cv-<br>13582 | Douglas & London   | No PFS Filed | PFS Due – 9/12/21  |
| 28. | Phillip Quinn v.<br>Hetero, et al.      | 21-cv-<br>16026 | Oliver Law         | No PFS Filed | PFS Due – 10/25/21 |
| 29. | E/O Tina<br>Schram v. ZHP,<br>et al.    | 21-cv-<br>17384 | Hollis Law         | No PFS Filed | PFS Due – 11/22/21 |
| 30. | Boyko Achkova<br>v. Rite Aid, et<br>al. | 21-cv-<br>10355 | Johnston Sztykiel  | No PFS Filed | PFS Due – 9/26/21  |

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| 31. | Dean Tasman v. | 23-cv- | Levin Papantonio | No PFS Filed | PFS Due – |
|-----|----------------|--------|------------------|--------------|-----------|
|     | ZHP, et al.    | 1399   |                  |              | 5/13/23   |
|     |                |        |                  |              |           |
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Respectfully submitted,

Clem C. Trischler

c: All counsel of record (via ECF)